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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/916,396	07/27/2001	Gregory M. Fahy	CENTMED.020A	7764

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EXAMINER

SAUCIER, SANDRA E

ART UNIT

PAPER NUMBER

1651

DATE MAILED: 06/16/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/916,396

Applicant(s)

Fahy

Examiner

Sandra Saucier

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— The MAILING DATE of this communication appears on the cover sheet with the correspondence address —

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Apr 7, 2003.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4 and 6-23 is/are pending in the application.
- 4a) Of the above, claim(s) 8 and 9 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 6, 7, 10-12, and 14-23 is/are rejected.
- 7) ☒ Claim(s) 13 is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

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DETAILED ACTION

Claims 1-4, 6-23 are pending. Claims 1-4, 6, 7, 10-23 are considered on the merits. Claims 8 and 9 are withdrawn from consideration as being drawn to a non-elected invention.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

NEW MATTER

Claims 1-7, 10-12, 14-20, 22 and 23 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention.

The insertion of "bicarbonate" in the independent claims 1, 19 and 20 so that they read "comprising bicarbonate, mannitol and lactose", is considered to be the insertion of new matter because "bicarbonate" is neither supported in the "Summary of the Invention" where the broadest statement of the invention should appear, nor was it present in the originally filed claims. It appears only in the examples, where it is limited to 10mM sodium bicarbonate. Use of "bicarbonate" implies a limitation range of from just above 0 to infinite mM as well as the use of any salt of bicarbonate such as potassium bicarbonate, lithium bicarbonate, calcium bicarbonate, etc... These concepts are not present in the specification as filed and are, therefore, considered to be new matter. Only insertion of 10mM sodium bicarbonate is supported. One is not free to expand the scope of the disclosure after filing and during prosecution.

The insertion of "glucose" in claims 10 and 11 is considered to be the insertion of new matter because "glucose" is neither supported in the "Summary of the Invention" where the broadest statement of the invention should appear, nor was it present in the originally filed claims. It appears only in the examples, where it is limited to 90mM glucose. Use of "glucose" implies a limitation range of from just above 0 to infinite mM. This concept is not present in the specification as filed and is, therefore, considered to be new matter. Only insertion of 90mM glucose is supported. One is not free to expand the scope of the disclosure after filing and during prosecution.

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Likewise in claim 12, insertion of the components listed in the claim without respective concentrations is not supported in the originally filed specification.

Please see *Gentry Gallery v. Berkline* 45 U.S.P.Q.2d 1498 for a discussion related to broadening the claimed invention without support in the as-filed specification. Please see *PurduePharma v. Faulding* 56 U.S.P.Q.2d 1481 for a discussion related to a failure to describe a claimed generic concept in the narrative portion of the specification, but rather basing support on limitations in examples.

INDEFINITE

Claim 7 remains rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 7 recites " comprises impermeants".

Classification of compounds into penetrating or permeant and non-penetrating or impermeants depends on the purported subject. There are also differences in the literature concerning the penetrating abilities of the same substance towards the same subject. See US 6,194,137 [A10], col. 6, line 41 where glucose is said to be an "impermeant chemical" and US 5,800,978 [B10], col. 15, l. 34 where glucose is said to be a "permeable" compound. Further, penetrating and non-penetrating appear to be relative terms, not mutually exclusive ones. See US 2002/0451156 [C10], col. 2, section 0010, for a discussion by one of skill in the art concerning the terms, permeable and non-permeable. In the present application, if one molecule of a compound penetrates the cell membrane, is this compound to be termed a "penetrating" one? In the absence of a definition, the meaning of permeant or penetrating vs. non-penetrating do not have definite metes and bounds, and is therefore indefinite.

Claim Rejections - 35 USC § 103

Claims 1-3, 7, 10-12, 14-16, 19, 22 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,194,137 [A10].

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The claims are directed to a solution to be used in the treatment of cell, tissue or organ with cryoprotectants comprising:

- 1) mannitol,
- 2) lactose,
- 3) bicarbonate
- 4) glucose
- 5) vitrifiable concentrations of cryoprotectants, DMSO, EG, formamide.

US 6,194,137 discloses compositions for use in cryoprotection of cells and tissues comprising:
any combination of cryoprotectants sufficient for vitrification (col. 6, l. 22) such as lactose and glucose (col. 6, l. 41) and DMSO, EG and formamide (col. 6, l. 24) in a vehicle such as Euro-Collins (col. 6, l. 66) which contains sodium bicarbonate (Table 1), and may include at least one osmotic buffering agent such as mannitol (col. 9, l. 27).

Claims 4, 17 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,194,137 [A10] as applied to claims 1-3, 7,10-12, 14-16, 19, 22, 23 above, and further in view of US 6,395,467 [E10].

The claims are directed to the inclusion of PVA type compounds in the solution.

US 6,395,467 discloses that PVA additives are very useful for enhancing the performance of biological cryopreservation solutions (col. 9, l. 44).

The inclusion of PVA in the composition of US 6,194,137 would have been obvious because US 6,395,467 teaches that PVA enhances the performance of biological cryopreservation solutions and '137 states that the solution may contain any combination of cryoprotectants sufficient for vitrification.

Claims 6, 18 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,194,137 [A10] as applied to claims 1-3, 7,10-12, 14-16, 19, 22, 23 above, and further in view of Klebe *et al.* [A12].

The claims are further directed to the inclusion of polyglycerol in the composition.

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Klebe *et al.* disclose that decaglycerol has cryoprotective properties and has been used solutions as a cryoprotectant for cells (abstract and Table 1).

The inclusion of decaglycerol as a cryoprotective agent in the solution of US 6,194,137 would have been obvious because Klebe *et al.* teach that decaglycerol, which is a polyglycerol, has cryoprotective properties and '137 teaches that any combination of cryoprotectants may be used (col. 6, l. 23).

All components of the composition as claimed have been used in the prior art for the same purpose as the instant purpose.

It is well known that it is prima facie obvious to combine two or more ingredients each of which is taught by the prior art to be useful for the same purpose in order to form a third composition which is useful for the same purpose. The idea for combining them flows logically from their having been used individually in the prior art. *In re* Pinten, 459 F.2d 1053, 173 USPQ 801 (CCPA 1972); *In re* Susi, 58 CCPA 1074, 1079-80; 440 F.2d 442, 445; 169 USPQ 423, 426 (1971); *In re* Crockett, 47 CCPA 1018, 1020-21; 279 F.2d 274, 276-277; 126 USPQ 186, 188 (1960).

Allowable Subject Matter

Claim 13 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Applicant's amendment necessitated the new grounds of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In

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no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1651. The supervisor for 1651 is M. Wityshyn, (703) 308-4743. The normal work schedule for Examiner Saucier is 8:30AM to 5:00 PM Monday, Tuesday and 8:30 AM to noon on Wednesday.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sandra Saucier whose telephone number is (703) 308-1084. Status inquiries must be directed to the Customer Service Desk at (703) 308-0197 or (703)-308-0198. The number of the Fax Center for the faxing of official papers is (703) 872-9306 or for after finals (703) 872-9307.



Sandra Saucier
Primary Examiner
Art Unit 1651
June 13, 2003